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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,672	10/10/2000	Yasir Skeiky	014058-009041US	2671
20350	7590	02/13/2006	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			SWARTZ, RODNEY P	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/688,672

Applicant(s)

SKEIKY ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11-27, 105-109 and 111-115 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-8, 11-18, 20-27, 105-109 and 111-115 is/are allowed.
- 6) ☒ Claim(s) 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Continued Examination Under 37 CFR 1.114**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 December 2005 has been entered.

Claims 1, 3, 4, 6, 7, 11, 12, 14, 15, 17, 18, 22, 105, 106, 107, 108, 109, 111, 112, 113, 114, and 115 have been amended.

2. Claims 1-8, 11-27, 105-109, and 111-115 are pending and under consideration.

### **Rejections Withdrawn**

3. The rejection of claim 5 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Pat. No. 6,592,877 is withdrawn in light of the amendment of claim 5.

Applicants argue that the subject of the claims of U.S. Pat. No. 6,592,877 is an isolated fusion protein comprising four *M. tuberculosis* antigens, i.e., TbRa3, Tb38-1, TbH4, and 38 kD. In contrast, instant claim 5 is directed to a composition containing a fusion protein comprising *M. tuberculosis* antigens MTb81, Mo2, TbRa3, 38kD, Tb38-1, and FL TbH4. In contrast, instant claim 19 is directed to a composition containing a fusion protein comprising at least two of *M. tuberculosis* antigens MTb81, Mo2, TbRa3, 38kD, Tb38-1, and FL TbH4, TbH9, MTCC#2, DPEP, DPPD, TbRa35, TbRa12, MTb59, MTb82, Erd14, FL TbRa35, DPV, MSL, MTI, ESAT-6,  $\alpha$ -crystalline, and 85 complex. The antigens listed as FL TbH4 and TbH4 are significantly different from each other not only in length, but also in the amino acid sequence.

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The examiner has considered applicants' argument, and finds it persuasive concerning instant claim 5.

4. The rejection of claim 6 under 35 U.S.C. 112, second paragraph, indefiniteness for rejection from a rejected claims, is withdrawn.

### **Rejections Maintained**

5. The rejection of claim 19 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Pat. No. 6,592,877 is maintained for reasons of record.

Applicants argue that the subject of the claims of U.S. Pat. No. 6,592,877 is an isolated fusion protein comprising four *M. tuberculosis* antigens, i.e., TbRa3, Tb38-1, TbH4, and 38 kD. In contrast, instant claim 5 is directed to a composition containing a fusion protein comprising *M. tuberculosis* antigens MTb81, Mo2, TbRa3, 38kD, Tb38-1, and FL TbH4. In contrast, instant claim 19 is directed to a composition containing a fusion protein comprising at least two of *M. tuberculosis* antigens MTb81, Mo2, TbRa3, 38kD, Tb38-1, and FL TbH4, TbH9, MTCC#2, DPEP, DPPD, TbRa35, TbRa12, MTb59, MTb82, Erd14, FL TbRa35, DPV, MSL, MTI, ESAT-6,  $\alpha$ -crystalline, and 85 complex. The antigens listed as FL TbH4 and TbH4 are significantly different from each other not only in length, but also in the amino acid sequence.

The examiner has considered applicants' argument, but does not find it persuasive for newly amended claim 19.

The sequences of TbRa3, Tb38-1, and 38 kD are identical in both the instant application and U.S. Pat. No. 6,592,877.

Claim 19 is directed to a fusion polypeptide comprising at least two heterologous isolated antigens from *M. tuberculosis* and a pharmaceutically-acceptable excipient. One

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embodiment is a fusion protein comprising **at least** TbRa3 and Tb38-1. Another embodiment is a fusion protein comprising **at least** TbRa3 and 38 kD. Another embodiment is a fusion protein comprising **at least** Tb38-1 and 38 kD. Another embodiment is a fusion protein comprising TbRa3, Tb38-1 and 38 kD. The open claim language allows for the embodiments to comprise more than the "at least two" isolated antigens.

Therefore, the embodiments of claims 1-3 of U.S. Pat. No. 6,592,877 do render claim 19 obvious.

### **Conclusion**

6. Claims 1-8, 11-18, 19-27, 105-109, and 111-115 appear to be allowable. Claim 19 is rejected.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.


If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

January 31, 2006